SOFEMED

CE
2803

OSTEOSYNTHESIS PLATES AND SCREWS

ATTENTION OPERATING SURGEON

PURPOSE:

Plates and bone screws are not active orthopaedic implants intended for single use to fix, correct and temporarily stabilise the bone structures to the bony perfect.

DESCRIPTION:

Plates and bone screws incorporate a wide variety of designs. The bone plates provide a means of bone fixation used for the reduction of the fractures and reconstructive surgery. These plates and screws osteosynthesis are intended only to assist healing and are not intended to replace normal bone structures.

MATERIALS:

AISI 316 LVM medical stainless steel according to ISO 5832-1.
Pure titanium medical grade according to ISO 5832-2.
Alloyed titanium medical grade according to ISO5832-3.

INDICATIONS:

1. Fresh Fractures
2. Osteotomy
3. Revision procedures where other treatments or devices have failed.
4. Arthrodesis

Patient selection factors to be considered include: 1) need for alignment and stabilization of bone fractures, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient.

Patient populations: All patient

Children under 12 Years old: there is no restriction of use. Clinical situation of the patient must be evaluated by the surgeon.

CONTRAINDICATIONS:

1. Infection
2. Patient conditions including blood supply limitations, obesity and insufficient quantity of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS:

Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone for withstand the stress placed upon the device by full or partial weight bearing of load bearing, particularly in the presence of non-union, delayed union, or incomplete healing. Internal fixation devices are internal splints that align the fracture until normal healing occurs. The size and shape of bones and soft tissue place limitation on the size and strength of implants. If there is delayed union or non-union of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographies examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Correct selection of the implants is extremely important. The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, of load bearing.
2. The devices can break when subjected to increased loading associated with non union or delayed union. Internal fixation devices are load sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, bend or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.
3. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
4. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws. Natches or scratches put in the implant during the course of surgery may contribute to breakage.
5. Remove after fracture has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding which may increase the risk of refracture in an active patient. The surgeon should weigh the risks verses benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.
6. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
7. Do not attempt screw fixation within a fracture line. Adequate fixation will be compromised if screws are placed within the fracture line.
8. Stainless steel implants are not compatible with MRI. Never use stainless steel and titanium implant components in the same construct
9. The implant is a short-term implant. In the event of the delay in bone consolidation, or if such consolidation does not take place, or if implantation is not carried out, complications may occur, for example fracture or loosing of the implant or instability of the implant system. Regular post-operative examinations are advisable.

SOFEMED international advice no more than 7 to 10 years of implantation in normal condition use.

PRECAUTIONS:

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for heir intended purpose. SOFEMED recommends that all instruments be regularly inspected for wear and disfigurement.

POSSIBLE ADVERSE EFFECTS:

1. Non-union or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Limb shortening due to compression of the fracture or bone resorption.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensation due to the presence of the device.
8. Nerve damage due to surgical trauma.
9. Necrosis of bone.
10. Postoperative bone fracture and pain.
11. Inadequate healing.
12. Infection
13. Embolism

CLEANING AND DECONTAMINATION:

Plates and screws must be disassembled and cleaned using neutral cleaners followed by a deionised water rinse before sterilisation and introduction into a sterile surgical department. Cleaning and disinfecting can be performed with aldhehyde-free solvents at higher temperatures. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some implants and instruments.

All products should be treated with care improper use handing may lead to damage and/or possible improper functioning of the device.

STERILIZATION:

Plates and screws are sold not sterile. They are recommended to be steam sterilized by health care institution according to the following process parameters:

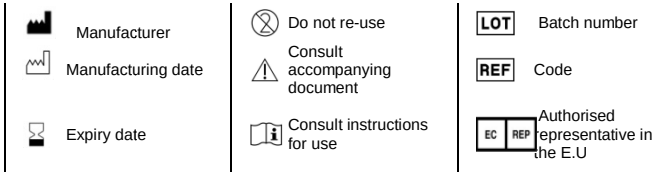
CYCLE	TEMPERATURE	EXPOSURE TIME
STEAM Gravity or pre-vacuum	134°C (273°F)	20 minutes

However, each health care institution must validate the technique and sterilization parameters used. Respect the regulations of your country if a law requires the sterilization parameters and technique to use. There is no limit for sterilization of instruments. However, it is necessary to check the condition of the equipment before use. All damaged material must be disposed of immediately. Do not re-sterilize if an implant is likely to have been in contact with human tissue or body fluids. Proceed to the immediate disposal to prevent its intended use.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or end user), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safely, effectiveness and/or performance, should notify his distributor or SOFEMED international. Further, if any of the implanted devices ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately by fax, written correspondence or e-mail. When filing a complaint, please provide the component(s) name and code, lot number(s), your name and address, the nature of the complaint and notification of the whether a written report from the distributor is requested.

SOFEMED International does not engage in a complaint handling process if the product information (such as essentially the batch number) is not provided by the complainant.



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